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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
HFI-35

60 8th Street, N.E.
Atlanta, Georgia 30309

October 7, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr James E. Thaxton, President
Georgia Turkey Farms, Inc.
Post Office Box 121
Watkinsville, Ga. 30677

WARNING LETTER

Dear Mr. Thaxton:

An inspection of you medicated feed mill located at Watkinsville, Georgia, conducted by Food and Drug Administration investigators on September 8-9, 1998, found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21, Code of Federal Regulations, Part 225). Such deviations cause medicated feeds being manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigation found failure to maintain a daily inventory record for each drug used; failure to maintain complete master record files, master labels, manufacturing instructions to include formulas to show mixing times, ingredient sequence, and assay frequencies; failure to have a written procedure for equipment clean out (flushes and/or physical cleaning) or disposal of flush material; failure to properly account for flushing materials being reworked into the feed; and failure to calibrate at least once a year the weighing scales used for the microhopper and the bulk ingredient scale hopper.

The above is not intended to be an all-inclusive list of CGMP violations. As a manufacturer of medicated and non-medicated feeds, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct these CGMP violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these CGMP violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction and/or notice of opportunity for a hearing on a proposal to withdraw approval of your Form FDA 1900s (Medicated Feed Applications) under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2). (This letter constitutes official notification under the law.) Based on the result of the September 8-9, 1998 inspection, evaluated together with the evidence before FDA when the Form FDA 1900s were

approved, the methods used in, or the facilities and control used for, the manufacture, processing, and packing of medicated feed are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

Until the CGMP violations have been corrected and the corrections verified by FDA, the Center for Veterinary Medicine will not approve medicated feed applications for your facility.

Your firm is already aware of 21 CFR 589.2000 and a copy of the Small Entities Compliance Guide was left with your firm.

You should notify this office in writing within 15 working days of receipt of this letter, of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the CGMP violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the address in the letterhead, attention Barbara A. Wood, Compliance Officer.

Sincerely,

Ballard H. Graham, Director
Atlanta District

cc: Mr. Timothy W. Lynn
General Manager